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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Abraham Loyter et al.  
 Serial No.: 10/511,990  
 Filed : October 21, 2004  
 For : ANTI-NLS SCFV AND PEPTIDES AND USES THEREOF  
 IN NUCLEAR IMPORT INHIBITION

1185 Avenue of the Americas  
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 July 28, 2005

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Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with the duty of disclosure under 37 C.F.R. §1.56, applicants direct the Examiner's attention to the following disclosures (**Exhibits 1-50**) which are listed on Form PTO-1449 (**Exhibit A**).

1. WO 99/28338, issued June 10, 1999 (**Exhibit 1**);
2. WO 00/49038, issued August 24, 2000 (**Exhibit 2**);
3. Adam, S.A. et al., (1992) Nuclear Protein Import Using Digitonin-Permeabilized Cells, *Methods in Enzymology*, 219, pp:97-110 (**Exhibit 3**);

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Page 2

4. Agostini, I. et al., (2000) Heat-Shock Protein 70 Can Replace Viral Protein R of HIV-1 during Nuclear Import of the Viral Preintegration Complex, *Experimental Cell Research*, 259, pp:398-403 (Exhibit 4);
5. Baeuerle, P.A., and D. Baltimore, (1988) I $\kappa$ B: A Specific Inhibitor of the NF- $\kappa$ B Transcription Factor, *Science*, 242, pp:540-546 (Exhibit 5);
6. Bailey, T.L. and C. Elkan, (1994) Fitting a Mixture Model by Expectation Maximization to Discover Motifs in Biopolymers, *Proceedings of the Second International Conference on Intelligent Systems for Molecular Biology*, pp:28-36 (Exhibit 6);
7. Baldrich-Rubio, E. et al., (2001) A Complex Human Immunodeficiency Virus Type 1 A/G/J Recombinant Virus Isolated from a Seronegative Patient with AIDS from Benin, West Africa, *Journal of General Virology*, 82(Pt.5), pp:1095-1106 (Exhibit 7);
8. Bouyac-Bertoia, M. et al., (2001) HIV-1 Infection Requires a Function Integrase NLS, *Molecular Cell*, 7(5), pp:1025-1035 (Exhibit 8);
9. Broder, Y.C. et al., (1997) Translocation of NLS-BSA Conjugates into Nuclei of Permeabilized Mammalian Cells Can Be Supported by Protoplast Extract: An Experimental

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System for Studying Plant Cytosolic Factors Involved in  
Nuclear Import, *FEBS Letters*, 412, pp:535-539 (Exhibit 9);

10. Bukrinsky, M. et al., (1992) Active Nuclear Import of Human Immunodeficiency Virus Type 1 Preintegration Complexes, *Proc. Natl. Acad. Sci. USA*, 89(14), pp: 6580-6584 (Exhibit 10);
11. Bukrinsky, M. et al., (1993a) A Nuclear Localization Signal Within HIV-1 Matrix Protein that Governs Infection of Non-Dividing Cells, *Nature*, 365, pp:666-669 (Exhibit 11);
12. Burinsky, M. et al., (1993b) Association of Integrase, Matrix, and Reverse Transcriptase Antigens of Human Immunodeficiency Virus Type 1 with Viral Nucleic Acids Following Acute Infection, *Proc. Natl. Acad. Sci. USA*, 90, pp:6125-6129 (Exhibit 12);
13. Choudhury, I. et al., (1998) Inhibition of HIV-1 Replication by a Tat RNA-Binding Domain Peptide Analog, *Journal of Acquired Immune Deficiency Syndromes & Human Retrovirology*, 17(2), pp:104-111 (Exhibit 13);
14. Cullen B.R., (1993) Does HIV-1 Tat Induce a Change in Viral Initiation Rights?, *Cell*, 73(3), pp.417-420 (Exhibit 14);
15. Cullen, B.R., (1995) Regulation of HIV Gene Expression, *AIDS*, 9(suppl. A) pp:S19-S32 (Exhibit 15);

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16. Cullen, B.R., (1998) HIV-1 Auxiliary Proteins: Making Connections in a Dying Cell, *Cell*, 93, pp:685-692 (Exhibit 16);
17. de Noronha, C.M. et al., (2001) Dynamic Disruptions in Nuclear Envelope Architecture and Integrity Induced by HIV-1 Vpr, *Science*, 294, pp: 1105-1108 (Exhibit 17);
18. Depienne, C. et al., (2000) Cellular Distribution and Karyophilic Properties of Matrix, Integrase, and Vpr Proteins from the Human and Simian Immunodeficiency Viruses, *Experimental Cell Research*, 260, pp:387-395 (Exhibit 18);
19. Dubrovsky, L. et al., (1995) Nuclear Localization Signal of HIV-1 as a Novel Target for Therapeutic Intervention, *Molecular Medicine*, 1(2), pp:217-230 (Exhibit 19);
20. F.C.L. Almeida and S.J. Opella, (1997) fd Coat Protein Structure in Membrane Environments: Structural Dynamics of the Loop Between the Hydrophobic Trans-Membrane Helix and the Amphipathic In-Plane Helix, *J. Mol. Biol.*, 270, pp: 481-495 (Exhibit 20);
21. Friedler, A. et al., (1998) Backbone Cyclic Peptide, Which Mimics the Nuclear Localization Signal of Human Immunodeficiency Virus Type 1 Matrix Protein, Inhibits

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22. Friedler, A. et al., (1999) Identification of a Nuclear Transport Inhibitory Signal (NTIS) in the Basic Domain of HIV-1 Vif Protein, *J. Mol. Biol.*, 289, pp:431-437 (Exhibit 22);
23. Gallay, P. et al., (1997) HIV-1 Infection of Nondividing Cells Through the Recognition of Integrase by the Importin/Karyopherin Pathway, *Proc. Natl. Acad. Sci. USA*, 94, pp:9825-9830 (Exhibit 23);
24. Goldfarb, D. and N. Michaud, (1991) Pathways for the Nuclear Transport of Proteins and RNAs, *Trends in Cell Biology*, 1, pp:20-24 (Exhibit 24);
25. Goldfarb, D.S. et al., (1986) Synthetic Peptides as Nuclear Localization Signals, *Nature*, 322, pp:641-644 (Exhibit 25);
26. Görlich, D., and I.W. Mattaj, (1996) Nucleocytoplasmic Transport, *Science*, 271, pp:1513-1518 (Exhibit 26);
27. Graessmann, M., and A. Graessmann, (1983) Microinjection of Tissue Culture Cells, *Methods in Enzymology*, 101, pp:482-493 (Exhibit 27);

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29. Harrison, J.L. et al., (1996) Screening of Phage Antibody Libraries, *Methods in Enzymology*, 267, pp:83-109 (Exhibit 29);
30. Heinzinger, N.K. et al., (1994) The Vpr Protein of Human Immunodeficiency Virus Type 1 Influences Nuclear Localization of Viral Nucleic Acids in Nondividing Host Cells, *Proc. Natl. Acad. Sci. USA*, 91, pp:7311-7315 (Exhibit 30);
31. Jenkins, Y. et al., (1998) Characterization of HIV-1 Vpr Nuclear Import: Analysis of Signals and Pathways, *J. Cell Biol.*, 143(4), pp:875-885 (Exhibit 31);
32. Johnsson, K. and L. Ge, (1999) Phage Display of Combinatorial Peptide and Protein Libraries and Their Applications in Biology and Chemistry, *Curr. Top. Microbiol. Immunol.*, 243, pp:87-105 (Exhibit 32);
33. Karni, O. et al., (1998) A peptide Derived from the N-terminal Region of HIV-1 Vpr Promotes Nuclear Import on Permeabilized Cells: Elucidation of the NLS Region of the Vpr, *FEBS*, 429, pp:7151-7158 (Exhibit 33);

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35. Laemmli, U.K., (1970) Cleavage of Structural Proteins during the Assembly of the Head of Bacteriophage T4, *Nature*, 227, pp:680-685 (Exhibit 35);
36. Lewis, P. et al., (1992) Human Immunodeficiency Virus Infection of Cells Arrested in the Cell Cycle, *The EMBO Journal*, 11(8), pp:3053-3058 (Exhibit 36);
37. Lewis, P.F. and M. Emerman, (1994) Passage through Mitosis Is Required for Oncoretroviruses but Not for the Human Immunodeficiency Virus, *Journal of Virology*, 68(1), pp:510-516 (Exhibit 37);
38. Luo, Z. et al., (1998) Structural Studies of Synthetic Peptide Fragments Derived from the HIV-1 Vpr Protein, *Biochemical and Biophysical Research Communications*, 244, pp:732-736 (Exhibit 38);
39. Nissam, A. et al., (1994) Antibody Fragments from a 'Single Pot' Phage Display Library as Immunochemical Reagents, *The EMBO Journal*, 13(3), pp:692-698 (Exhibit 39);

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41. Piller, S. et al., (1996) Vpr Protein of Human Immunodeficiency Virus Type 1 Forms Cation-Selective Channels in Planar Lipid Bilayers, *Proc. Natl. Acad. Sci. USA*, 93, pp:111-115 (Exhibit 41);
42. Pollard, V.W. and M. H. Malim, (1998) The HIV-1 Rev Protein, *Annu. Rev. Microbiol.*, 52, pp:491-532 (Exhibit 42);
43. Popov, S. et al., (1998) Viral Protein R Regulates Nuclear Import of the HIV-1 Pre-Integration Complex, *The EMBO Journal*, 17(4), pp:909-917 (Exhibit 43);
44. Rasched, I. and E. Oberer, (1986) Ff Coliphages: Structural and Function Relationships, *Microbiological Reviews*, 50(4), pp:401-427 (Exhibit 44);
45. Schneider, J. et al., (1988) A Mutant SV40 Large T Antigen Interferes with Nuclear Localization of a Heterologous Protein, *Cell*, 54, pp:117-125 (Exhibit 45);
46. Simm, L.G. et al., (1993) Human Immunodeficiency Virus Type 1 DNA Synthesis, Integration, and Efficient Viral



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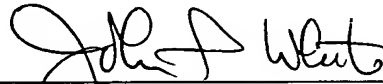
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48. Truant, R. and B.R. Cullen, (1999) The Arginine-Rich Domains Present In Human Immunodeficiency Virus Type 1 Tat and Rev Function as Direct Importin  $\beta$ -Dependent Nuclear Localization Signals, *Molecular and Cellular Biology*, 19(2), pp:1210-1217 (Exhibit 48);
49. Wecker, K. and B.P. Roques, (1999) NMR Structure of the (1-51) N-terminal Domain of the HIV-1 regulatory protein Vpr, *Eur. J. Biochem.*, 266, pp:359-369 (Exhibit 49); and
50. Yuan, X. et al., (1990) Human Immunodeficiency Virus vpr Gene Encodes a Virion-Associated Protein, *AIDS Research and Human Retroviruses*, 6(11), pp:1265-1271 (Exhibit 50).

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

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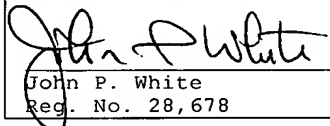
Respectfully submitted,



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# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

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## **Complete if Known**

Sheet 2 of 6

Application Number 10/511,990  
Filing Date October 21, 2004  
First Named Inventor LOYTER Abraham  
Art Unit  
Examiner Name  
Attorney Docket Number 73236

## **NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	CA	Adam, S.A. et al. (1992) Methods in Enzymology 219, 97-110.	
	CB	Agostini, I. et al. (2000) Exp Cell Res 259, 398-403	
	CC	Baeuerle, P.A., and D. Baltimore (1988) Science 242, 540-546	
	CD	Bailey, T.L., and C. Elkan (1994) Fitting a mixture model by expectation maximization to discover motifs. Proceedings of the Second International Conference on Intelligent Systems for Molecular Biology 28-36	
	CE	Baldrich-Rubio, E. et al. (2001) J Gen Virol 82(Pt5), 1095-106	
	CF	Bouyac-Bertoia, M. et al. (2001) Mol Cell 7(5), 1025-35	
	CG	Broder, Y.C. et al. (1997) FEBS Lett. 412, 535-539	
	CH	Bukrinsky, M. et al. (1992) PNAS USA 89(14), 6580-4	
	CI	Bukrinsky, M.I. et al. (1993a) Nature 365, 666-669	
	CJ	Bukrinsky, M. et al. (1993b) PNAS USA 90, 6125-6129	

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	CK	Choudhury, I., J. Wang, et al. (1998) Journal of acquired immuno-deficiency syndromes and human retrovirology 17, 104-111	
	CL	Cullen, B.R. (1993) Cell 73(3), 417-20	
	CM	Cullen, B.R. (1995) Aids 9, S19-32	
	CN	Cullen, B.R. (1998) Cell 93, 685-692	
	CO	de Noronha, C. M. et al. (2001) Science 294(5544): 1105-8	
	CP	Depienne, C. et al. (2000) Exp Cell Res 260, 387-395	
	CQ	Dubrovsky, L. et al. (1995) Molecular Medicine 1(2), 217-230	
	CR	F.C.L. Almeida and S.J. Opella (1997) J. Mol. Biol. 270, 481-495	
	CS	Friedler, A. et al. (1998) Biochemistry 37, 5616-5622	
	CT	Friedler, A. et al. (1999) J Mol Biol 289, 431-437	

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	CU	Gallay, P. et al. (1997) Proc. Natl. Acad.Sci. USA 94, 9825-9830	
	CV	Goldfarb, D., and N. Michaud (1991) Trends Cell Biol. 1, 20-24	
	CW	Goldfarb, D.S. et al. (1986) Nature 322, 641-644	
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	CY	Graessmann, M. and A. Graessmann (1983) Methods Enzymol. 101, 482-92	
	CZ	Haffar, O.K. et al. (2000) J Mol Biol 299, 359-68	
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	DE	Karni, O. et al. (1998) FEBS Let. 429:421-425	
	DF	Koostra, N.A., and H. Schuitemaker (1999) Virology 253(2), 170-180	
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	DH	Lewis, P. et al. (1992) EMBO J 11, 3053-3058	
	DI	Lewis, P.F., and Emerman, M. (1994) J. Virol. 68, 510-516	
	DJ	Luo, Z. et al. (1998) BBRC 244, 732-736	
	DK	Nissim, A. et al. (1994) EMBO J 13, 692-698	
	DL	Petit, C. et al. (2000) J Virol 74(15), 7119-26	
	DM	Piller, S.C. et al. (1996) Proc Natl Acad Sci 93, 111-115	
	DN	Pollard, V.W., and M.H. Malim (1998) Annu. Rev. Microbiol. 52, 491-532	

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	DO	Popov, S. et al. (1998) EMBO J 17, 909-917	
	DP	Rasched, I., and E. Oberer (1986) Microbiol. Rev. 50(4), 401-27	
	DQ	Schneider, J. et al. (1988) Cell 54, 117-125	
	DR	Simm, L.G. et al. (1993) J Virol 67(7), 3969-77	
	DS	Thompson, J.D. et al (1994) Nucl. Acids Res. 22, 4673-4680	
	DT	Truant, R., and B.R. Cullen (1999) Mol Cell Biol 19, 1210-1217	
	DU	Wecker, K., and B.P. Roques (1999) Eur J Biochem 266, 359-369	
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